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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,477	06/23/2003	Thomas J. Boyd	IR 7348-03	7235

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EXAMINER	
KRASS, FREDERICK F	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 09/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/601,477	BOYD ET AL.	
	Examiner	Art Unit	
	Frederick F. Krass	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-8 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-8 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date A & B.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Informalities

The following informality is noted and should be corrected in responding to this Office action:

Claim 8 does not end in a period.

Indefiniteness Rejection

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1) Claim 1 is incomplete insofar as the variable "n" in the structural formula is not defined.

2) Claim 8, the recitation of an oral "spray" - a liquid composition - is non-sequitur in view of the recitation of a "solid base" in claim 1. Furthermore, an oral spray is not what one would normally consider a "confectionary composition".

Explanation/correction is required.

Anticipation Rejection

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1) Claims 1-4 and 8 are rejected under 35 U.S.C. 102(a) as being anticipated by Beltran et al (WO 03/034842).

The prior art discloses the use of the hydrochloride salt of ethyl lauroyl arginine ("LAE") as a preservative for food products in amounts of 0.0001 to 1 percent by weight (p. 4, first paragraph). Such products include fruit juices (p. 4, line 11) and chewing gums (p. 4, third-to-last line). It is the examiner's position that an "oral spray" as recited in claim 8 is read upon by any orally acceptable liquid composition, including fruit juices, since a "spray" is merely a liquid that is intended to be atomized, and statements of intended use generally carry no weight in determining patentability.

2) Claims 1, 3 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Saito et al (USP 3,825,560).

The prior art discloses the use of arginine long-chain alkyl ester salts falling within the scope of the instantly claimed structural formula (see the passage bridging col. 2, line 68 to col. 4, line 31) as preservatives for foods, including sweet sake (again an "oral spray"). See col. 7, lines 29-37; see also working example 11, wherein sucrose is included as a sweetener for a (solid) fish meat base to make a sweet sake preconcentrate. Note also working example 13, wherein a sweetened wet dentifrice containing 3 percent by weight arginine long-chain alkyl ester salt (falling within the percentage range recited by instant claim 3) is disclosed.

Obviousness Rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1) Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Saito et al (USP 3,825,560).

The prior art is discussed in detail in subsection "2)" of the "Anticipation" section supra, and differs from the instant claim insofar as it does not specifically disclose (by name or specific formula) the

hydrochloride salt of ethyl lauroyl arginine ("LAE"). That compound is, however, clearly within the scope of the generic formula provided at the top of col. 3. And, moreover, the hydrochloride salt of methyl lauroyl arginine, LAE's methyl homologue, is specifically disclosed, tested, and included in various working example formulations: see for example col. 4, lines 20 and 21; the third compound of Table I at col. 4; col. 7, line 5; and col. 8, line 16.

It is well-settled that when chemical compounds have "very close" structural similarities and similar utilities, without more a prima facie case may be made. See In re Deuel, 51 F.3d 1552, 1559 (Fed. Cir. 1995). The necessary motivation to make the claimed compound, and thus the prima facie case of obviousness, arises from the reasonable expectation that compounds similar in structure will have similar properties. In re Gyurik, 596 F.2d 1012, 1018 (1979). The classic example of "very close" structural similarity is that of adjacent homologues. Accordingly, it would have been obvious to have used LAE, the methyl homologue of the specifically disclosed hydrochloride methyl lauroyl arginine salt of the prior art, as a preservative for sweet sake and its concentrates as disclosed therein, since the compounds have "very close" structural similarities and the same utility, consonant with the reasoning of the cited precedent.

2) Claim 2 is rejected under 35 USC 103(a) as being unpatentable over Saito et al (USP 3,825,560) in view of Beltran et al (WO 03/034842).

The primary reference is discussed in subsection "2)" of the "Anticipation" section supra and, as described therein, differs from the instant claim insofar as it does not disclose (by name or specific formula) the hydrochloride salt of ethyl lauroyl arginine ("LAE"), although same is clearly within the scope of the general structural formulae provided therein. The secondary reference teaches that LAE is particularly ideal as a preservative for foods, including juices, wines and other alcoholic beverages (p. 4, lines 9 et seq.), because of its remarkable spectrum of antimicrobial activity (p. 1, last paragraph). Accordingly, it would have been obvious to have used LAE as a preservative for the sweet sake and its concentrates of the primary reference, motivated by the desire to obtain the remarkable spectrum of antimicrobial activity expected for same as taught by the secondary reference.

3) Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beltran et al (WO 03/034842) in view of Yang et al (USP 4,695,463).

The primary reference discloses the use of the hydrochloride salt of ethyl lauroyl arginine ("LAE") as a preservative for food products in amounts of 0.0001 to 1 percent by weight (p. 4, first paragraph). Such products include confectionaries generally, an example given being chewing gum (p. 4, last four lines on the page). It differs from the instant claims insofar as it is silent regarding tablet, lozenge or bead confectionaries specifically.

The secondary reference illustrates the state of the confectionary art, and teaches that various equivalent forms of confectionaries including chewing gums, lozenges and tablets can be used interchangeably depending on the particular "texture" desired, i.e. to provide a specific form most appealing to a given user. See col. 8, lines 52-67. Also useful for the same purposes are flavor beads (see especially example IV at col. 11), which can also be added to other confectionaries, such as chewing gums (col. 1, lines 5-12). Since the secondary reference is cited as a teaching reference demonstrating the general state of the confectionary art, it differs from the instant claims insofar as it silent regarding long-chain alkyl arginine ester salts.

It would have been obvious to have prepared the confectionary compositions of the primary reference in any of a number of forms, including the chewing gums specifically disclosed therein, as well as equivalent forms such as lozenges, tablets and beads, motivated by the desire to tailor particular products to specific users as taught by the secondary reference.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick F. Krass whose telephone number is 571-272-0580. The examiner's schedule is 9:30AM – 6:00PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass
Primary Examiner
Art Unit 1614